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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,320	06/25/2003	Dwayne Lee Looney	ETH-5072	3099

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EXAMINER

SILVERMAN, ERIC E

ART UNIT PAPER NUMBER

1615

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/603,320	Applicant(s) LOONEY ET AL.	
	Examiner Eric E. Silverman, PhD	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.  
     4a) Of the above claim(s) 22-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/28/04, 7/2/03, 3/15/04, 1/24/05, 7/2/03</u> | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 – 21, drawn to a composition, classified in class 424, subclass 443.
- II. Claims 22 - 28, drawn to a method of making a hemosatic device and a product made by that method, classified in class 424, subclass 443.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by a materially different process, such as by first forming the product and then partially oxidizing the cellulose, as taught by WO 98/0446 on pages 7 – 9.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The search of both groups in the same application would pose a serious burden on the examiner.

During a telephone conversation with Blossom Loo on 2-10-06 a provisional election was made with traverse to prosecute the invention of I, claims 1 - 21. Affirmation of this election must be made by applicant in replying to this Office action. Claims 22 – 28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Information Disclosure Statement***

The European Application EP 0216378 listed on Applicant's Information Disclosure Statement is in German. Examiner has considered only the Abstract, since this is the only portion of the document for which an English translation was provided.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 8, 17, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claims recite fibers with a particle size. As fibers are by definition anisotropic, it is unclear to which dimension the limitation of particle size refers. Clarification is requested.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 – 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0216378 (378), English Abstract Only, of record either by itself or in combination with Blazicek et al., CAPLUS 1987:219652 (of record, Blazicek).

378 teaches a haemostatic material basted on fibrous particles which is cross-linked with an adhesive. Carboxycellulose and microcrystalline cellulose and their alkali metal (i.e. sodium) salts are suggested as haemostatics. Preferred adhesives are methylcellulose, HPMC, methylhydroxyethylcellulose, and methylhydroxypropyl cellulose. The ratio of the adhesives particles to the haemostatic particles is at least 1 to 10. Furthermore, the composition is taught to be useful for preparation of use forms, such as for stomatology and otorhinolaryngology, which the artisan would understand to mean for use in haemostatic devices.

378 does not teach the particle sizes.

Nonetheless, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to alter the particle size in order to achieve the best possible result. Absent the showing of an unexpected result, the artisan would consider find it a simple matter to optimize this parameter, and would not require undue

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experimentation to do so. The expected result would be an effective haemostatic composition and device comprising the same.

Blazicek teaches compositions of fibrous oxidized cellulose mixed with a binder such as sodium carboxymethylcellulose for use in ointments, pastes, and gels. Blazicek suggests a particle size of 400 microns (0.4 mm) for the carboxymethylcellulose.

Accordingly, it would further be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use the particle size taught by Blazicek. The motivation to do so is that Blazicek teaches the composition to be useful in ointments, pastes, and gels. Thus, the artisan who desired to use the composition of 378, which has similar components to that of Blazicek, in these dosage forms, would choose the particle sizes taught by Blazicek in order to achieve a composition suitable for such uses.

It is noted that the particle sizes taught by Blazicek are near to, but not in the ranges recited by claims 8 and 18. Nonetheless, absent an unexpected result relating to the particle size, the artisan would find it obvious to optimize the particle size in order to achieve the best possible result. The artisan would consider find it a simple matter to optimize this parameter, and would not require undue experimentation to do so. The expected result would be an effective haemostatic composition and device comprising the same.

Claims 1 – 4, 7 – 14, 17 – 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO/98/00446 (446), of record, either by itself or in combination with Blazicek, of record.

446 teaches oligosaccharides, such as oxidized regenerated cellulose and suggests their use in wound dressings (haemostatic devices) (abstract, claim 5). 446 further teaches that preferred materials are woven or knitted fabrics, which the artisan would understand includes fibers (page 1, lines 26 – 27). 446 also suggests mixing the oxidized cellulose with other polysaccharides in order to form compositions with novel properties, for instance, combining oxidized cellulose with chitosan is taught to be useful to form haemostatic compositions (page 3, lines 30 – 37).

446 does not teach the particle sizes.

Nonetheless, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to optimize the particle size in order to achieve the best possible result. Absent the showing of an unexpected result, the artisan would consider find it a simple matter to optimize this parameter, and would not require undue experimentation to do so. The expected result would be an effective haemostatic composition and device comprising the same. The teachings of Blazicek are discussed above.

Accordingly, it would further be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use the particle size taught by Blazicek. The motivation to do so is that Blazicek teaches the composition to be useful in ointments, pastes, and gels. Thus, the artisan who desired to use the composition of 378, which

has similar components to that of Blazicek, in these dosage forms, would choose the particle sizes taught by Blazicek in order to achieve a composition suitable for such uses.

It is noted that the particle sizes taught by Blazicek are near to, but not in the ranges recited by claims 8 and 18. Nonetheless, absent an unexpected result relating to the particle size, the artisan would find it obvious to optimize the particle size in order to achieve the best possible result. The artisan would consider find it a simple matter to optimize this parameter, and would not require undue experimentation to do so. The expected result would be an effective haemostatic composition and device comprising the same.

Claims 1 – 4, and 9 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hudson et al., US 6,306,154 either by itself or in combination with Blazicek.

Hudson teaches materials and methods for facilitating haemostasis (col. 1, lines 9 – 12). The composition comprises a mixture of carboxymethylcellulose (CMC) fibers with reinforcing fibers (col. 2, lines 46 – 49). The product is made by knitting a tube from a cellulose fiber and then converting the cellulose partially into sodium carboxymethyl cellulose (col. 5, line 60 – col. 6, line 14). As such, the artisan would understand the final composition to be haemostatic device comprising fibers of both cellulose and sodium carboxymethyl cellulose.

Hudson does not teach the particle size of the fibers.

Nonetheless, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to optimize the particle size in order to achieve the best possible result. Absent the showing of an unexpected result, the artisan would consider find it a simple matter to optimize this parameter, and would not require undue experimentation to do so. The expected result would be an effective haemostatic composition and device comprising the same. The teachings of Blazicek are discussed above.

Accordingly, it would further be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use the particle size taught by Blazicek. The motivation to do so is that Blazicek teaches the composition to be useful in ointments, pastes, and gels. Thus, the artisan who desired to use the composition of 378, which has similar components to that of Blazicek, in these dosage forms, would choose the particle sizes taught by Blazicek in order to achieve a composition suitable for such uses.

It is noted that the particle sizes taught by Blazicek are near to, but not in the ranges recited by claims 8 and 18. Nonetheless, absent an unexpected result relating to the particle size, the artisan would find it obvious to optimize the particle size in order to achieve the best possible result. The artisan would consider find it a simple matter to optimize this parameter, and would not require undue experimentation to do so. The expected result would be an effective haemostatic composition and device comprising the same.

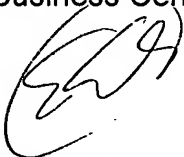
**Conclusion**

No claims are allowed. No claims are free of the prior art.\

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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